

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the foregoing amendments and the following remarks.

Claim Status

Claim 13 was cancelled. Claims 1-12 and 14-16 are pending. No new matter was added.

Double Patenting Rejection

Claims 1-12 and 14-16 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 10, 12-13, 16 and 18-20 of co-pending Application No. 10/588,696. Additionally, claims 12 and 14-16 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8 and 18 of co-pending Application No. 10/588,695. Applicant traverses.

Applicant is filing a terminal disclaimer herewith, with reference to co-pending Application Nos. 10/588,695 and 10/588,696, each filed on February 15, 2005. In light of this action, Applicant requests that the Examiner remove the

provisional rejection of claims 1-12 and 14-16 and the claims be allowed.

\$102/103 Claim Rejections

Claims 1, 4, 8-12, 14 and 16 stand rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C §103(a) as obvious over U.S. Patent Application No. 2004/0045897 (hereinafter Nakabayashi) as evidenced by Developments in Medical Polymers for Biomaterials Applications, KATZ (hereinafter Katz). Applicant traverses.

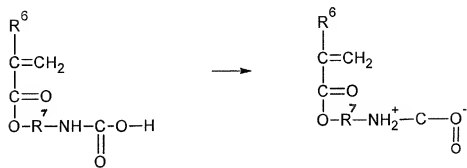
As stated in the previous office action, to anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may

only rely on 35 U.S.C. §103. See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

Nakabayashi does not disclose a method for production of an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer as is described in the instant invention. On page 3 of the instant office action, the Examiner states that the MPC copolymer used by Nakabayashi contains a fixed negative charge. (Lines 18-20). The Examiner refers to the molecular structure of the MPC copolymer as shown by Katz. However, the Examiner then correctly concludes that the MPC copolymer is zwitterionic and therefore has a net zero charge. (Lines 20-22).

Referring now to claim 1, the Examiner opines that the copolymer of the MPC-monomer and the vinylpolymerizable monomer of formula (3) would at least render obvious a polyelectrolyte with a fixed negative charge in the precipitant system, if in said formula (3) the substituent R⁸ is a hydrogen atom. However, according to the most basic knowledge of those persons skilled in the art, the monomer of formula (3) in the case where R⁸ is a hydrogen atom immediately transforms into a zwitterion having a net zero charge as illustrated below for a monomer unit. This occurs due to the acidic character of the hydrogen and due to

the basic character of the nitrogen (N) with its free electron pair. Naturally, the same holds true if the monomer unit is part of the copolymer with MPC.



Thus, in the membrane disclosed in Nakabayashi, no polyelectrolyte having a negative fixed charge is present, Consequently, neither the process of claim 1 nor the product of claim 12 of the instant application are obvious over Nakabayashi. Accordingly, Nakabayashi does not disclose all of the elements of either claim 1 or claim 12, and hence, does not anticipate claim 1 or claim 12. Therefore, this rejection must fail.

Referring now to the claims which depend on claims 1 and 12, there appears to be a misunderstanding/misinterpretation by the Examiner with respect to the current office action. Referring to the end of page 3 through the first paragraph on page 4 (and also including page 5 with respect to claim 12) of

the current office action, the Examiner alleges that Nakabayashi discloses the inclusion of a vinyl-polymerizable monomer wherein R^8 is a hydrogen atom "that is polymerized in the inner lumen dynamically during injection." The Examiner then refers to Examples 1-8 of Nakabayashi. (Page 4, Lines 1-3).

After thoroughly reviewing Examples 1-8 of Nakabayashi, there is no disclosure at all of a dynamic polymerization during injection. Example 1 clearly states that to a 40% aqueous solution of DMAC a copolymer of MPC and methacryloyloxyethyl phenyl carbamate was added. There is no dynamic polymerization during injection, but a readily reacted copolymer is added to the internal coagulation solution. The same holds true for Examples 2-7.

Looking now to claim 4 (Page 4, Lines 6-7 and Page 7, Lines 7-8 of the current office action), the Examiner states that Nakabayashi discloses that the dissolved interior filler precipitates in contact with the spinning solution. This statement suggests that the Examiner believes that the interior filler is a specific component that is dissolved (in some medium) and that this specific component precipitates in contact with the spinning solution. With all due respect to the Examiner, this statement does not make any sense and would not

be made by one who is skilled in the art. The interior filler as such is a solution of different components. This is demonstrated in Example 1 of Nakabayashi where the interior filler (or internal coagulate solution) consists of a 40% aqueous solution of DMAC. To this solution 1% of a copolymer of MPC and methacryloyloxyethyl phenyl carbamate is added **resulting in the complete interior filler**. Additionally, there is nothing disclosed in the Examples of Nakabayashi that any part of the interior filler coagulates after coming into contact with the spinning solution. The interior filler (interior coagulate solution) causes the polymer in the membrane-forming raw material solution to coagulate. This is fundamental knowledge of one of ordinary skill in the art.

According to claim 4 of the instant invention, the polyelectrolyte which is dissolved in the precipitation system precipitates in contact with the spinning solution. This means that the polyelectrolyte does not dissolve in the spinning solution. There is no disclosure or even a hint within Nakabayashi that such an incompatibility of the polyelectrolyte with the membrane-forming raw material solution existed, resulting in the precipitation of the polyelectrolyte when brought into contact with the spinning solution.

Looking now to claim 16, there appears to be an additional misunderstanding/misinterpretation on the part of the Examiner. Looking to Page 5, Lines 13-15 of the current office action (and also on Page 8, Lines 16-20), the Examiner alleges that Nakabayashi discloses that the membrane is chemically modified with an agent which reacts with the polyelectrolyte having a negative fixed charge while referring to Pages 4-5, Paragraphs 40-41 of Nakabayashi. This allegation could not be further from the truth as Nakabayashi is completely silent regarding such a disclosure. Paragraphs 40 and 41 simply state that the spinning solution and the hollow space inner solution are brought into contact with one another which leads to coagulation of the spinning solution. During coagulation, the MPC polymer is entangled with the molecule chains of the membrane forming polymer or are incorporate into dense structures near the surface, thereby firmly immobilizing the MPC polymer. **However, this is a pure physical immobilization without any chemical modification.** In fact, there is no chemical reaction to speak of.

In reference to claims 4, 8-11, 14 and 16, "[I]f an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. *Kovin Assoc.*

v. Exttech/Exterior Technologies, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002). Thus, claims 4, 8-11, 14 and 16 are not unpatentable over Nakabayashi and should be allowed.

§103 Claim Rejections

Claims 1-12 and 14-16 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,604,208 (hereinafter Chu) in combination with U.S. Patent Application No. 2004/0045897 (hereinafter Nakabayashi). Applicant traverses.

The above comments regarding Nakabayashi and Katz are incorporated herein. As stated above, Nakabayashi does not disclose a method for production of an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer as disclosed in claim 1. Additionally, Nakabayashi also fails to disclose an integrally asymmetric membrane with at least one separating layer and a supporting layer, characterised in that a polyelectrolyte with negative fixed charges is physically bound in the separating layer and characterised in that the supporting layer is free from polyelectrolyte as disclosed in claim 12.

As stated in the previous office action, MPEP § 2143 "Basic Requirements of a *Prima Facie* Case of Obviousness" states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations.

Regarding the third criterion, the court has stated that "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicant contends that none of the prior art references, neither Chu, nor Nakabayashi, alone or in combination, teach, suggest, or provide a motivation for a method for production of an integrally asymmetric membrane as disclosed in claims 1-11. Additionally, Applicant contends that none of the prior art references, neither Chu, nor Nakabayashi, alone or in combination, teach, suggest, or provide a motivation for an integrally asymmetric membrane as disclosed in either claim 12 or claims 14-16.

The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above and below, it is clear that Chu and Nakabayashi fail to teach or suggest all the limitations of Applicant's claims.

It is unmistakable that Chu discloses microporous membranes which are skinless. (Chu, Claim 1). Based on this fact, it is also clear that the membranes of Chu do not exhibit a separating layer as required in claims 1-12 and 14-16 of the instant invention. Furthermore, the charge modifying agent in the membranes of Chu is bonded to substantially all of the microstructure of the microporous membrane. (Chu, Claim 1). Substantially all of the internal microstructure means substantially all of the external surface and internal pore surfaces. (Column 9, Lines 22-24). Thus, it is clear that for

the skinless membranes disclosed in Chu, essentially no part of the microstructure is free from polyelectrolyte. For the membranes of Chu, it is important to have the anionic charge modifying agent bonded to substantially all of the microstructure throughout the membrane in order to obtain the properties required for the membranes of Chu (i.e. an improved effective filtration rating for cationic submicronic particulate contaminants and a decreased adsorptive capacity for anionic submicronic particulates). (Column 13, Lines 34-45). This is contrary to claim 12 of the instant invention which requires that the supporting layer of the membrane be free from polyelectrolyte. Additionally, a polyelectrolyte with fixed negative charges is physically bonded to the separation layer of the membranes of the instant invention only.

Moreover, Chu fails to disclose a process or method for the production of an integrally asymmetric membrane with a least one separating layer and a supporting layer adjoining the separation layer as described in claim 1 of the instant invention. As previously mentioned, Chu discloses a skinless membrane having a micro-structure throughout the membrane. (Chu, Abstract). Additionally, Chu fails to disclose a method wherein the precipitation system comprises a polyelectrolyte with negative fixed charges. According to Chu, the process for applying and

binding the modifying amount of an anionic charge modifying agent to substantially all of the membrane microstructure preferably comprises contacting a readily prepared membrane with an aqueous solution of the anionic charge modifying agent (i.e. the membrane is impregnated with that solution). (Column 11, Lines 56-65). With such a process it is impossible to produce a membrane with a polyelectrolyte having negative fixed charges physically bound in a specific layer only. According to claim 12 of the instant invention, a membrane can be produced by the process of claim 1 which requires the process step that the precipitant system which is used for the formation of the separating layer of the membrane comprises a polyelectrolyte with negative fixed charges. There is no disclosure within Chu of such a process step.

As a side note, membranes produced by a process like the one disclosed in Chu, (i.e. membranes which after having been completely precipitated are provided with a polyelectrolyte) do not show an improvement in separation efficiency due to the interlocking and entanglement of the polymer chains of the polyelectrolyte with those of the membrane forming polymer being hardly possible. (Specification, Page 15, Paragraph 1). Thus, Chu does not relate at all to either the membranes or the

process for their production as are the subject matter of claims 1-12 and 14-16 of the instant application.

Beginning with the membranes and the method of their production described by Chu, there is no reason to mention Nakabayashi which is also relied on by the Examiner. Nakabayashi relates to membranes having an improved surface hydrophilicity. (Nakabayashi, Abstract). The membranes of Nakabayashi have a copolymer of MPC held on the surface of the membrane, whereby the copolymer is present on the surface in a higher concentration than in other parts of the membrane. "(T)he amount of MPC copolymer present in pores in the inner parts of membrane (thick membrane areas) should be as small as possible, but the MPC copolymer should be unevenly distributed only on the surface of the hollow fiber membrane." (Paragraph 32, Lines 6-10). Thus, the distribution of the modifying agent in the membranes of Nakabayashi is contrary to the distribution in the membranes of Chu.

Chu relates to membranes having a charge modifying agent bonded to substantially all of the microstructure of the microporous membranes in order to have an improved effective filtration rating for cationic submicronic particulate contaminants and a decreased adsorptive capacity for anionic

submicronic particulate (see above). Motivation may be lacking when the state of the art at the time of the invention in question was discovered pointed researchers in a different direction than the inventor proceeded. Indeed, the Federal Circuit has repeatedly recognized that proceeding contrary to the accepted wisdom in the art represents "strong evidence of unobviousness." *In re Hedges*, 783 F.2d 1038, 1041, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986); *W.L Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552, 220 U.S.P.Q. 303, 312 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (prior art teaching that conventional polypropylene should have reduced crystallinity before stretching and should undergo slow stretching, led away from claimed process of producing porous article by expanding highly crystalline PTFE by rapid stretching); accord *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988). There is no reason for one skill in the art to refer to a teaching which is directed to membranes having a modifying agent unevenly distributed only on the surface of the membrane. Such a membrane be more than just a modification of the membranes of Chu, it would be a membrane which is completely different in that it aims at different properties. Clearly, Nakabayashi teaches away from Chu. One of ordinary skill in the art would not have been motivated as alleged by the Examiner on Page 8 of the current office action.

Additionally, there is no advantage with respect to the efficiency of the process by discharging a modifying agent in the inner lumen during the production of the membrane thereby reducing the number of steps. There would only be such an advantage if the membrane obtained by such a process would lead to the same product. This is, however, not the case. By the process of Nakabayashi, the modifying agent is applied to the membrane surface only, and is not bonded throughout the membrane structure as required by Chu. Consequently, the properties of the resulting membranes are different. Also, to re-emphasize our previous comments, Nakabayashi does not disclose polyelectrolytes with negative fixed charges. As the Examiner correctly concludes, the MPC copolymer used by Nakabayashi is zwitterionic and therefore has a net zero charge.

Accordingly, Chu in view of Nakabayashi does not disclose all of the elements of claims 1 and 12. Therefore, this rejection must fail. Thus, claims 1 and 12 are not anticipated by Chu and Nakabayashi and should be allowed.

In reference to claims 2-11 and 14-16, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious. *Hartness Int'l, Inc. v.*

Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Thus, claims 2-11 and 14-16 are not unpatentable over Chu in view of Nakabayashi and should be allowed.

No new matter has been added.

Conclusion

In view of the foregoing, Applicant respectfully requests an early Notice of Allowance in this application.

Respectfully submitted,



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